

Article 34 Annexure

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CLAIMS

1. A test device for use in automated testing apparatus comprising:
a substrate of predetermined size and shape, so as to facilitate handling by said
automated testing apparatus, and including at least one indentation or aperture
wherein said indentation or aperture is of a predetermined location, size and
shape with respect to said automatic testing apparatus; and further comprising
supportive material mounted on at least a part of said substrate so as to be at
least partially positioned over said indentation or aperture; and wherein said
supportive material comprises a guide means characterised by a sample
deposition portion and attached thereto a channel portion including an indicator
means; whereby the positioning of a sample to be tested on said sample travelling
along said channel portion and interacting with said indicator means so as to
provide a measure of the adequacy of the fluid sample collected.

2. A test device according to Claim 1 wherein said supportive material is
spaced from an outer most surface of said substrate.

3. A test device according to Claims 1 or 2 wherein said supportive material
is sandwiched between two substrates.

4. A test device according to any preceding claim wherein said substrate is
provided with a plurality of said indentations or apertures

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claim 1

6. A test device according to any preceding claim comprising a holding means, whereby the handling of said test device by automated apparatus is facilitated.

Claim 7

claim 1

7. A test device according to any preceding claim, wherein at least a part of at least one surface of said supportive material is provided with a suitable hydrophobic material.

Claim 8

8. A test device according to Claim 7 wherein said hydrophobic material is latex or wax or the like.

claim 1

9. A test device according to any preceding claim wherein said substrate is provided with at least one second indentation or aperture suitably sized and shaped and positioned, with respect to said first aperture, so as to be aligned with said channel portion of said guide means.

10. A test device according to Claim 9 wherein said indentation or aperture is positioned so as to be aligned with said indicator means.

Claim 11

11. A test device according to any preceding Claim 1, wherein said indicator means is associated with, or impregnated with, or cross-linked to, or coated onto, at least a part of at least one surface of said supportive material.

12. A test device according to any preceding Claim 1, wherein said sample deposition portion is circular and the diameter of same is greater than the

13. A test device according to Claim 12 wherein said sample deposition diameter is greater or in the region of 1 to 5mm.

Claim 1
④ 14. A test device according to any preceding claim wherein said supportive material, or at least a part of said supportive material, is adapted to efficiently and quickly distribute a fluid sample into at least a part of the supportive material or across at least part of said supportive material.

Claim 1
④ 15. A test device according to any preceding claim wherein said supportive material is absorbent in nature.

Claim 1
④ 16. A test device according to any preceding claim wherein said supportive material comprises a hydrophobic membrane.

Claim 1
④ 17. A test device according to any preceding claim wherein said supportive material is provided with colourmetric and/or fluorometric and/or luminometric and/or radiometric indicator means whereby fluid samples may be analysed.

Claim 1
④ 18. A test device according to any preceding claim wherein said device is provided with identification means.

Claim 1
④ 19. A pouch that is of a size and shape that corresponds to the size and shape of the test device according to any preceding claim.

④ 20. A pouch according to Claim 19 wherein said pouch comprises a desiccant.

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21. A pouch according to Claim 20 wherein said desiccant comprises at least a part of at least one surface of said pouch.

22. A pouch according to Claims 20 or 21 wherein said desiccant is provided on an inner surface of said pouch.

Claim 20

Q 23. A pouch according to ~~Claims 20 to 22~~ wherein said pouch comprises a desiccant surface which is so sized and shaped so that when the test device is inserted into the pouch the supportive material contained in the test device is opposite, or adjacent, the desiccant.

Claim 20

Q 24. A pouch according to ~~Claims 20-23~~ wherein said desiccant comprises silica gel.

Claim 19

25. A pouch according to ~~Claims 19-24~~ wherein at least a part of its outer surface is made from impervious material.

Sub A
26. A test kit comprising at least one test device according to Claims 1 to 18 and at least one pouch according to Claims 19-25.

Sub B
27. A test kit according to Claim 26 comprising a means for obtaining a sample.

28. A test kit according to Claim 27 wherein said means for obtaining a sample comprises a lance or blade, if a blood sample is required; a pipette if a saliva sample is required; and/or a container if a urine and/or stool sample is required.

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Claim 26

29. A test kit according to ~~Claims 26-28~~ comprising instructions and/or a barcode for identifying purposes.

30. A test kit according to Claim 29 wherein an identification means is provided to indicate the identity and origin of each individual test device, the type of test to be carried out and/or the particular shape of the test device whereby automated testing apparatus can be automatically re-configured following reading of the identification means to accommodate test devices of a variety of shapes and for a variety of tests.

31. A method for confirming the adequacy of a collected fluid sample using the test device according to ~~Claims 1-18~~, comprising;

(i) providing a substrate of a predetermined size and shape, and including at least one indentation or aperture wherein said indentation or aperture is of a predetermined location, size and shape so as to facilitate handling by an automated testing apparatus; and further comprising a supportive material mounted on at least a part of said substrate so as to be at least partially positioned over said indentation or aperture; wherein said supportive material comprises a guide means characterised by a sample deposition portion and attached thereto a channel portion including an indicator means;

(ii) placing a fluid sample on said sample deposition portion and allowing said fluid sample to fill and/or permeate into said channel

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(iii) collecting sufficient fluid of said sample so that said sample passes over said indicator means in or associated with said channel portion;

(iv) assessing said collected fluid sample by visualisation of said indicator means and/or by automated machine analysis of said indicator means.

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